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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,845	10/18/2001	Samy Ashkar	CMCC 779	7069

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	09/981,845	ASHKAR ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Finality of the rejection of the last Office Action (13 February 2004) is *withdrawn* in view of the new grounds of rejection set forth below.

Status of Application, Amendments and/or Claims

The amendment filed 11 May 2004 has been entered in full. Claims 7-18 were cancelled. Claims 1-6 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the specification, as set forth at page 3 of the previous Office Action (13 February 2004), is *withdrawn* in view of the amendment (11 May 2004).

The rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, written description, new matter, as set forth at pages 3-4 of the previous Office Action (13 February 2004), is *withdrawn* in view of the amendment, (11 May 2004).

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as set forth at page 8 of the previous Office Action (13 February 2004), is *withdrawn* in view of the amendment, (11 May 2004).

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

an osteopontin-derived peptide fragment comprising the amino acid of SEQ ID NO:11 wherein the peptide increases cell attachment of *osteoprogenitor cells* to a material and increases cell spread of *osteoprogenitor cells,*

does not reasonably provide enablement for:

an osteopontin-derived peptide comprising the amino acid of SEQ ID NO:11 which binds *any integrin receptors* on the surface on *any cell type*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (21 August 2003).

Applicant submits that the guidance and ease in carrying out the specification's described assays, as shown in the examples, would clearly enable one to treat coated plates with other types of cells expressing different types of receptor/integrin molecules, and assay for cell attachment and/or cell spread. Applicant argues that cell attachment and spread can additionally be measured by the change in cell volume to surface area, as well as the formation of stress fibers. Applicant states that the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question

provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

Applicant's arguments have been fully considered but are not deemed persuasive. The specification discloses that when plates are coated with SEQ ID NO:11, **only osteoprogenitor cells attach and spread to the surface** (Emphasis added). Thus human osteoprogenitor cells have a receptor which recognizes SEQ ID NO:11, causing the osteoprogenitor cells to attach and spread to the surface. The specification fails to teach other cell types which have SEQ ID NO:11 binding receptors. Applicant elected stem cells, however, stem cells are the precursor to a number of diverse types of cells. The specification fails to teach if integrins are found on all of these cells and if there are different receptors that bind osteopontin-derived peptides. The specification fails to teach how to differentiate between an integrin receptor and another cell surface molecule that binds SEQ ID NO:11. Contrary to Applicant's assertion, it would require an indeterminate quantity of fundamentally unpredictable investigational experimentation of the skilled artisan to determine which type of receptor bound SEQ ID NO:11 and then discern which cell type carried that specific receptor.

Furthermore, the specification only teaches that antibodies to $\alpha_v\beta_3$ integrin significantly diminish SEQ ID NO:15 (mOC-1016) from binding to cells (page 53, lines 17-21 and page 54). The specification never discloses which integrin antibody inhibited SEQ ID NO:11 from binding. **Thus, it is not clear if the cell surface receptor that binds SEQ ID NO:11 is even an integrin receptor because the specification never disclosed a specific integrin antibody that inhibited SEQ ID NO:11 from binding**

(Emphasis added). There is no predictability as to which integrin receptor would bind SEQ ID NO:11 because the specification only discloses that antibodies to $\alpha_v\beta_3$ integrin inhibited SEQ ID NO:15 from binding (Table 8, page 54). Table 8 in the instant specification illustrates that antibodies to different integrins may be used to block binding to specific integrins, but only antibodies to $\alpha_v\beta_3$ integrin were able to inhibit SEQ ID NO:15 (mOC-1016), **not SEQ ID NO:11, from binding** (Table 8, page 54) (Emphasis added). The specification fails to teach which integrin receptor (if indeed it is an integrin receptor) would bind SEQ ID NO:11.

The instant specification teaches that osteoprogenitor cells attach and spread to surfaces coated with SEQ ID NOs:9-15 (page 53, line 22-page 54, line 2) and only antibodies to $\alpha_v\beta_3$ integrin significantly diminish SEQ ID NO:15 from binding. This means that SEQ ID NO:15 binds the $\alpha_v\beta_3$ integrin receptor. However, this is not tantamount to SEQ ID NO:11 (or any other osteopontin-derived peptide) binding any integrin on any cell type. This is demonstrated by the fact that SEQ ID NO:15 was able to cause osteoprogenitor cells to attach and spread in the presence of antibodies against CD44 and $\alpha\beta1$ (page 54). This means that SEQ ID NO:15 does not bind integrin receptors CD44 and $\alpha\beta1$. Thus not all osteopontin-derived peptide fragments can bind any type of integrin receptor.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
3/1/05

Elizabeth C. Kemmerer

PRIMARY EXAMINER